

REMARKS

Claims 1-25 remain under consideration in this application.

Rejection under 35 U.S.C. § 112

Applicant respectfully submits that claims 24 and 25 do not lack enablement in the specification pursuant to 35 U.S.C. § 112, first paragraph. The specification does, in fact, enable one of ordinary skill in the art to administer the claimed composition to prevent parasitic infection. Page 8, lines 4-6, of the specification clearly states that the parasitocidal formulation of the present invention can be used to treat infected animals or to prevent infestations in non-infected animals. It further provides a regimen for preventing infestations, namely, administering the formulation once per month. There is further support in the specification for preventing parasitic infestation at page 1, lines 11-12, and page 2, lines 18-20.

The Examiner states that the claim of utility in preventing parasitic infestations is not believable on its face. The only support the Examiner has for his disbelief is his unsupported assertion that the level of ordinary skill in the art for preventing parasite infection is low, thus requiring higher direction and guidance. Applicant respectfully submits that the Examiner's unsupported statements are not sufficient to establish that the present claims are not enabled. Applicant submits that sufficient direction and guidance are given to enable one skilled in the art to prevent parasitic infestations using Applicant's formulation. Applicant submits that one skilled in the art would understand that parasitic infestations can be both treated and prevented using the parasitocidal formulation of the present invention.

Rejections under 35 U.S.C. § 102(b)

The Examiner has rejected claims 1-10, 12, 13 and 16 under 35 U.S.C. § 102(b) as being anticipated by JP 59027819 ("JP '819"). Contrary to the Examiner's assertions, JP '819 does not teach a milk chocolate composition comprising 15-60% pyrantel pamoate. The Examiner appears to have misread JP '819. JP '819 indicates that the composition may contain 15-60 parts pyrantel pamoate, not percentage of pyrantel pamoate. The composition disclosed in JP '819

contains three components: pyrvinium pamoate (10-50 parts), pyrantel pamoate (15-60 parts) and milk chocolate (975-890 parts). Even if highest amount of pyrantel pamoate was used in combination with the lowest amounts of the other ingredients, the amount of pyrantel pamoate in the composition of JP '819 would be only 6.25%. This is well below Applicant's claimed amount of cestocidal agent, which is equal to or greater than about 17% w/w. Thus, JP '819 does not anticipate claims 1-10, 12, 13 or 16, all of which require an amount of cestocidal agent equal to or greater than about 17% w/w.

Nor does JP '819 render claims 1-10, 12, 13 or 16 obvious. Applicant's claims require a composition comprising equal to or greater than about 17% w/w of a cestocidal agent (i.e. pyrantel) or equal to or greater than about 50% of the salt of the cestocidal agent (i.e. pyrantel pamoate). JP '819 discloses the use of a maximum of only 6.25% pyrantel pamoate. The amount of cestocidal agent required by Applicant's claims is significantly higher than that disclosed by JP '819. Such a significant difference simply cannot be considered obvious.

Rejections under 35 U.S.C. § 103(a)

Applicant respectfully submits that a *prima facie* case of obviousness for rejecting the pending claims has not been established. Claim 11, which was rejected under 35 U.S.C. § 103(a) as being obvious over JP '819, is not obvious in view of this reference. For the reasons discussed above, JP '819's disclosure of 6.25% pyrantel pamoate in no way discloses or suggests claim 11, which requires about 62% w/w pyrantel pamoate or another pyrantel salt.

Claims 19, 24 and 25, which were rejected under 35 U.S.C. § 103(a) as being obvious over Burger et al. (ZA 9104494), are not obvious in view of this reference. Claim 19 requires a salt of a cestocidal agent in an amount equal to or greater than 50% w/w. Claims 24 and 25 require a cestocidal agent in an amount equal to or greater than about 17% w/w. Burger et al. does not specify any amount of cestocidal agent. As a result, the specific amounts required by Applicant's claims cannot be considered obvious over the teaching of Burger et al.

The Examiner acknowledges that Burger et al. does not disclose the specific amount of cestocidal agent required by the claims. However, he argues that it would have been obvious to one having ordinary skill in the art to determine the optimum amount of pyrantel pamoate and that it is “very possible” the optimum amount would have fallen within the broad range of 17% or greater. Applicant submits that these arguments fail to establish a case of *prima facie* obviousness.

Firstly, the mere possibility that if the amount of pyrantel pamoate in Burger et al.’s formulation was optimized it could fall within Applicant’s claimed range of 17% or greater is not a sufficient basis to support a *prima facie* case of obviousness. Secondly, as noted in the present application, page 7, line 19 to page 8, line 3, the formulation of the present invention allows for a higher suspended solids content of cestocidal agents than was foreseen as being possible from the prior art. As a result, Applicant’s formulation can deliver a higher dosage of cestocidal agent in a lower volume than was attainable in the prior art. Prior compositions required the use of at least two syringes to deliver the dose of pyrantel required to effectively treat tapeworms. The amounts of cestocidal agent required by the claims are significant in that a sufficient dosage of a composition containing at least about 17% w/w cestocidal agent, or 50% w/w salt of a cestocidal agent, can be delivered in a single 36 ml syringe. Thus, the increased concentration achieved by the formulation of the present invention is not simply a result of determining the optimum amount of pyrantel pamoate to use. Rather, it is a breakthrough, unattainable in the prior art, that allows delivery of an effective amount of cestocidal agent in a single syringe. As a result, claims 19, 24 and 25 are in no way obvious over the general disclosure contained in Burger et al.

Furthermore, claim 25 specifically requires that the formulation be administered to equine to treat *Anoplocephala perfoliata* infestation. Burger et al. in no way discloses or suggests administration to equine or treatment of *Anoplocephala perfoliata* infestation, providing another reason claim 25 is not obvious over Burger et al.

Double Patenting Rejections


Claims 1-25 have been rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-14 of U.S. Patent No. 6,596,714 and claims 1-25 of U.S. Patent No. 6,207,179. Applicant submits herewith a properly executed terminal disclaimer, with the appropriate fee, to overcome these double patenting rejections.

No grounds for rejecting claims 14, 15, 17-18 and 20-23, other than double patenting rejections that have been overcome by a terminal disclaimer, have been provided. Applicant submits that these claims, along with the other claims discussed herein, are patentable over JP '819 and Burger et al.

In view of the foregoing amendments and remarks, it is respectfully submitted that the claims are now in condition for allowance and eventual issuance. Such action is respectfully requested. Should the Examiner have any further questions or comments which need be addressed in order to obtain allowance, he is invited to contact the undersigned attorney at the number listed below.

Acknowledgment of receipt is respectfully requested.

Respectfully submitted,

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